

provided by Applicants' apparatus which kills tissue contacting the heated bladder. The structural differences in the Doering apparatus and Applicants' device are a consequence of the different purposes for which they are used.

In other words, an important purpose of Doering in designing his apparatus was to avoid tissue damage which is in complete conflict with Applicants' purpose of necrosing tissue. Given these conflicting purposes, Doering cannot be properly combined with the secondary references for teaching or suggesting anything about making a device for necrosing tissue. At the top of page 2, of the translation Doering contrasts his device with conventional diathermy electrodes noting the danger of overdosing and burning, and that self-treatment with such devices is impossible.

Clearly, it is only with the benefit of Applicants' disclosure of why and how an apparatus for necrosing tissue should be made that the Examiner can focus on Doering's teachings to suggest an apparatus intended to avoid burning tissue. In retrospect the differences between Applicants' apparatus and that of Doering may seem simple and small to the Examiner but the proper perspective for evaluating Doering's teachings is what one of ordinary skill in the art could have learned from them. From that perspective Doering would not have taught anything useful in making Applicants' invention. It should not be overlooked when considering the question of obviousness in this case that the medical establishment has moved toward complicated and expensive laser technology to necrose body cavity lining (uterine). If a simple and inexpensive heated balloon was an obvious approach, why didn't

someone do it before, especially when one further considers that Doering has been available since 1953.

Spears is directed to a balloon-tipped catheter which emits heat to fuse together fragmented sections of plaque in the arterial wall in the region of a stenosis (or obstruction), which region normally suffers from undesired cracking, tearing and stretching caused by contact of the inflated balloon with the vessel wall during balloon angioplasty (col. 2, line 66 to col. 3, line 22). In addition, as abrupt restenosis or reclosing of the vessel may occur if torn tissue and plaque become dislodged, it is desirous that the vessel wall treatment result in the smoothing of the stenosed region. In other words, the apparatus of Spears is directed to the restoration and rehabilitation of the arterial wall and the creation of a smooth, cylindrically-shaped channel. (col. 2, lines 28-29). In contrast, Applicants' invention is directed to a method for effecting cauterization necrosis.

The Spears reference adds nothing meaningful to the teachings of Doering. In contrast to Applicants' invention, the Spears disclosure is directed to a balloon-tipped catheter including means for heating the disrupted tissues of the plaque and arterial wall in order to fuse together fragmented segments of tissue lining an arterial wall and to coagulate blood trapped within planes of tissue and within fissures created by wall fracture to produce a smooth, cylindrically-shaped channel. (Col. 2, lines 24-29). Applicants' invention is not directed to fusing together fragmented segments of plaque in an artery or to producing a smooth, cylindrically-shaped channel in arteries. The present invention is directed instead to the cauterization necrosis of tissue lining a human body cavity and particularly

the endometrium of the uterus. The composition of plaque is very different from the tissues lining mammalian body cavities such as the endometrial lining of the uterus and Spears does not teach or suggest that his method of fusing fragmented segments of plaque in an artery may be employed for cauterization necrosis or that it has applications for cauterizing the tissues of the uterus. Moreover, blood vessels are not body cavities in the sense that they are filled with blood in a living patient and Spears teaches that his invention has specific application in arteries such as the coronary, renal, iliac, femoral, popliteal, and carotid arteries. (Col. 3, lines 23-31).

Furthermore, Spears does not teach or suggest the specific parameters of temperature and duration disclosed by Applicants to effect cauterization necrosis of tissue. Applicants disclose that the temperature range for effecting tissue necrosis is about 190° to about 215°F and preferably about 210°F and should be applied for about 4 to 12 minutes and preferably around 6 minutes. As noted at page 1, line 14 of the specification, the term necrosis is defined as "the death of cells in tissue." With respect to the endometrium, the intent of such necrosis is to minimize bleeding. Spears is not concerned with minimizing bleeding. On the contrary, Spears is directed to a completely different purpose, i.e., the fusion of fragmented sections of plaque. Accordingly, Applicants respectfully submit that the objects of Spears are distinctly different from those of the present invention and those differences are reflected in the structure of the Spears device.

Accordingly, Applicants respectfully submit that the rejections of claims 21, 23, and 24 which are directed to a

method for effecting the necrosis of the tissue lining a body cavity is improper and should be withdrawn.

Applicants believe that this application is now in condition for allowance and such action is respectfully requested. If the Examiner believes that the prosecution of this case could be advanced by contact with Applicants' attorney he is invited to contact the undersigned at the number given below.

Respectfully submitted,

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